IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LP MATTHEWS, L.L.C.,) REDACTED PUBLIC VERSION
Plaintiff,)
v.) C.A. No. 04-1507-SLR
BATH & BODY WORKS, INC.; LIMITED BRANDS, INC.; KAO BRANDS CO.)))
(f/k/a THE ANDREW JERGENS COMPANY); and KAO CORPORATION,)
Defendants.)

LP MATTHEWS' OPPOSITION TO BATH & BODY WORKS, INC.'S AND LIMITED BRANDS, INC.'S MOTION FOR SUMMARY **JUDGMENT OF INVALIDITY UNDER 35 U.S.C. § 103**

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Dated: July 27, 2006 171479.1

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NATURE AND STAGE OF PROCEEDINGS

On December 8, 2004, plaintiff LP Matthews, L.L.C. filed a Complaint for patent infringement against defendants Kao Brands Company (formerly known as The Andrew Jergens Company) ("KBC"), Kao Corporation, Limited Brands, Inc., and Bath & Body Works, Inc. (D.I. 1.) LP Matthews amended its Complaint on February 2, 2005. (D.I. 5, 8.) This Court entered a Scheduling Order on June 9, 2005. (D.I. 39.) Fact discovery closed on January 27, 2006. (D.I. 39.) Expert discovery closed on May 12, 2006. (D.I. 39.) On June 29, 2006, the parties filed Opening Claim Construction Briefs. (D.I. 244, 254, 255.) On July 6, 2006, the Limited defendants filed this Motion for Summary Judgment of Invalidity under 35 U.S.C. § 103. (D.I. 268, 270.) This Answering Brief opposes that motion.

SUMMARY OF THE ARGUMENT

The Limited defendants' arguments echo KBC's arguments that claims 6 and 9 of the '062 patent are invalid as obvious based on a 1996 decision by the Board of Patent Appeals and Interferences ("the Board"). (See D.I. 245, 246, 300.) The Limited defendants interject into this argument a manual directed to the manufacture of dry soaps. (LEx. C.2) That reference, however, is cumulative of references before the examiner during prosecution of the patent-in-suit. Because it introduces neither new fact nor new law, the Limited defendants' motion should be denied for the same reasons stated in LP Matthews' Opposition to KBC's Motion for Summary Judgment based on Subsequent Board Decision. (D.I. 300.)

In their brief, at best, the Limited defendants ignore the differences between orange oil and d-limonene that even their own liability expert and corporate designee recognize. At

1 Limited Brands, Inc. and Bath & Body Works, Inc are "the Limited defendants."

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² "LBR refers to the Limited defendants' Opening Brief in Support of their Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 103. "LEx." refers to an exhibit cited in the declaration of David M. Hill, Esq. in

worst, they deliberately misrepresent the phrases "citric oil" and "citrus oil" in prior art that clearly discloses only d-limonene-containing compositions. Even their expert concedes this. Differences between orange oil and d-limonene alone compel denial of their motion, emphatically, in fact, since the '062 examiner had before him English versions of the same references and an opportunity to consider exactly the same argument the Limited defendants make today.

Thus, the Limited defendants disregard differences between orange oil and dlimonene that they knew about as a corporation. Then, they rely upon a Board decision that ignored the indisputable fact that orange oil was not a component of any prior art composition before it. Even if orange oil had been so disclosed, there is no evidence of its use as a cleaning agent for human skin. Moreover, neither the Limited defendants nor the Board identify any teaching, motivation or suggestion to combine the prior art they cite. And genine disputed facts exist regarding secondary indicia of non-obviousness, including at least commercial success, long felt need, and unexpected results.

STATEMENT OF FACTS

A. During Prosecution of the '062 Patent-In-Suit, the Inventors Overcame the Patent Office's Concerns About Obviousness of Claims 6 And 9 by Pointing Out That Their Invention Claimed Use of Orange Oil, not d-Limonene.

The inventors submitted their application for what would eventually become the '062 patent, for "Cleaning Compositions with Orange Oil," on September 27, 1989. Many of the original application claims were rejected by the examiner under 35 U.S.C. §103 over the prior art Coleman, Dellutri, and Juliano references. (Ex. 1.) In response, the inventors argued that the cited references actually taught away from using orange oil to clean human

support of LBR. "Ex." refers to exhibits cited in this brief.

skin because prior art d-limonene references required distillation of a different, natural substance (oil from citrus fruits or other plants). (Ex. 2.) As a result, the examiner allowed the claims. (Ex. 3.)

B. The Continuation-In-Part Application Process Resulted in a Deficient Sua Sponte Board Decision on the Patentability of Application Claim 25.

On November 4, 1991, the '062 patent inventors filed a continuation-in-part application based on the '062 patent application. The inventors immediately disclosed Coleman and Dellutri. After the new examiner finally rejected the CIP for inadequacies in the written description, the applicants appealed to the Board. On April 15, 1997, the Board maintained the written description rejection and, sua sponte, added a rejection for obviousness under 35 U.S.C. § 103. (LEx. G.) The new, un-briefed rejection applied Coleman and Dellutri for an orange oil claim element, apparently not considering the Section 103 rejection in the patent application. The Board also cited the 1969 and 1989 editions of the Physicians' Desk Reference (PDR), respectively, for the oat claim element and a completely different application element calling for a towelette. (See LEx. G at 12.) The Board did not state that the oat ingredient in PDR 1969 was an emulsifying agent. (Id.) The inventors disputed the Board's rejection for obviousness and then abandoned the application.

In its sua sponte Section 103 rejection, the Board discussed Coleman and Dellutri independently. Coleman, it said, "describes the use of d-limonene obtained from citrus oils, such as orange oil, as a hand cleaner" and concluded that "emollients or moisturizers...are conventionally used in combination with d-limonene." (LEx. G at 9.) The Board did not say Coleman recites orange oil or citrus oil or citric oil. REDACTED

(Ex. 4, Carson Tr. at 215-16.) Dellutri "also describes cleaning agents that can be used as a hand cleaner which include d-limonene obtained from orange oil" and

"aloe vera extract [that] may be used as an optional ingredient." Id. The Board did not say Dellutri discloses orange oil or citrus oil or citric oil.

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(Ex. 4 at 202-04), contradicting the Limited defendants' representation otherwise, e.g., page 10 of their brief. The Board also said that PDR 1969 disclosed that "colloidal oatmeal has long been used to treat skin" and that "skin care compositions should be adjusted to have a pH approximate to that of normal skin." (Ex. 1 at 10-11.) Like PDR 1969, Juliano discloses colloidal oatmeal, making the PDR cumulative. (Compare Ex. 2 with LEx. E.) The Board said PDR 1989 disclosed skin care compositions impregnated on a towelet and "hermetically sealed in packet" (which may have been relevant to the prosecution of the CIP). (LEx. G at 12.) But the Board did not identify a single reason to combine these references, or discuss the level of ordinary skill in the art, both of which are required to find obviousness. The Board, nevertheless, wrote that application claim 25 would have been obvious.

Paradoxically, even as the Board reached its conclusion that application claim 25 would have been obvious, it directed the examiner to look for more prior art. (LEx. G at 6-7.) The Board's decision says nothing of the '062 patent application. And while the Board chastises the new examiner, for example, for searching only one subclass of prior art (LEx. G at 5-7, cited in LBR), the examiner of the '062 patent searched three. (LEx. A at cover page.) The Limited defendants, like the Board, ignored that fact, just as they ignore the facts required for a finding of obviousness.

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ARGUMENT

A. Summary Judgment Is Not Appropriate Since Genuine Disputes of Material Fact Exist.

Obviousness is a question of law based on underlying facts. Those facts are (1) the scope and content of the prior art, (2) whether the combined references disclose each and every element of the asserted claim, (3) the differences between the prior art and claims at issue, (4) the level of ordinary skill in the art, and (5) a teaching or motivation to combine the elements of the prior art into the claimed invention. See, e.g., Graham v. John Deere Co., 383 U.S. 1, 17-18 (1961); C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1352 (Fed. Cir. 1998). Because each of these facts is material, none can be disputed for summary judgment to be proper. Fed. R. Civ. P. 56(c), see, e.g., Paragon Podiatry Lab. v. KLM Lab., 984 F.2d 1182, 1184-85 (Fed.Cir.1993). LP Matthews disputes underlying facts (1), (2), (3), and (5). These disputes are genuine.

Additionally, there exist factual inquiries regarding secondary indicia of nonobviousness. And the Limited defendants' reliance on the Board's decision is misplaced
because it does not address these fact issues and comes six years too late. Both the Limited
defendants' opening brief and the Board's decision are wrought with genuinely disputed
material facts. LP Matthews has already briefed the Board's decision and incorporates it
here. (D.I. 300.) To recap, the decision is legally deficient, refers to a different invention
than the '062 patent, was based on a lower standard of proof than is required to prove
invalidity, and presented conclusions that were successfully traversed during prosecution of
the '062 patent application. (Id., generally.) The decision is also inadmissible and cannot
form the basis of a summary judgment motion. (Id.)

Turning to the genuinely disputed facts underlying this obviousness case, the Coleman and Dellutri references disclose compositions that contain d-limonene as a cleaning component. Where a citrus oil is disclosed, it is only as a source of d-limonene. The examples of the composition in Coleman show that only d-limonene issued. Likewise, Dellutri actually defines "citric oil" as d-limonene (with chemical stabilizers). These arguments and these references were before the examiner, who clearly appreciated that dlimonene and orange oil were different.

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Thus, even if the use of d-limonene as a cleaning agent had been suggested by prior art, the inventors' use of undistilled orange oil makes their invention patentably distinct.

And the applicants also points out this possible synergy between d-limonene and other orange oil constituents: "[O]ther esters and volatiles in the orange oil may contribute to the enhanced cleaning properties...." (Ex. 1.)

The Limited defendants did not identify a prior art reference that recites orange oil as a cleaning component in a composition that cleans human skin. Because no single reference discloses orange oil as a cleaning component, the Limited defendants' motion should be denied.

Because no combination of references discloses a composition according to claim 6

or claim 9, the Limited defendants' motion should be denied. Additionally (and alternatively), fact disputes exist regarding differences between d-limonene and orange oil that bear on the scope of the prior art, and the differences between the prior art and claims 6 and 9 - both of which are necessary underlying facts for a determination of obviousness. Finally, the Limited defendants do not identify a clear and convincing teaching, motivation or suggestion to combine in their opening brief, failing to carry their burden to prove no dispute of that fact underlying an obviousness determination. They cite without explanation the 1996 Board decision and no other reference for that motivation to combine references. (LBR at 9-10.) But obviousness depends on the facts at the time that the patent application was filed; hindsight is improper. In re Kahn, 441 F.3d 977, 986 (Fed. Cir. 2006) (reversing board for not explaining motivation-suggestion-teaching requirement). Like the Board here and the Board in Kahn, the Limited defendants fail to explain the motivation-suggestionteaching requirement of Section 103 - and, since the '062 patent issued, their burden is even higher (clear and convincing) than the Board's (preponderance). (See D.I. 300 at 7.) Because the Limited defendants echo KBC's other obviousness arguments, LP Matthews incorporates its opposition here, and respectfully requests denial of the Limited defendants' motion for the same reasons as those stated in D.I. 300.

B. Secondary Indicia of Non-obviousness Raise Fact Issues for Trial or Defeat that Defense

A case for obviousness may be rebutted with evidence of so-called secondary indicia of non-obviousness, including commercial success, long felt need and unexpected results.

See Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17 (1966).

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The inventors' own product, Healthy Kleaner, was marketed from 1989, and was just beginning to have some success when, in January, 1992, the Food and Drug Administration reclassifed Healthy Kleaner from a soap to an "adjunct to a medical device." The inventors were, in fact, victims of their own success –it was the fact that hospitals discovered that Healthy Kleaner was very good at removing bandage adhesive residue that caused the reclassification and recall. (Ex. 6 at 116:2-7, 118-20, 142-145; Ex. 7.)

These commercial successes indicate non-obviousness of the '062 invention.

Unexpected results like those reported to the '062 patent examiner are another indicator of non-obviousness. See, e.g., Kao Corp. v. Unilever U.S., Inc., 441 F.3d 963, 970 (Fed. Cir. 2006). The Limited defendants themselves produced documents that, even today, indicate orange oil is used for fragrance, not cleaning. (Ex. 7 at 9097.) These indicators form a factual basis for the rejection of the Limited defendants' motion.

Finally, testimonials by customers of Healthy Kleaner reflect long felt need and praise by others, further indicating that the '062 patent claims 6 and 9 are not obvious. (Ex. 8.)

CONCLUSION

Claims 6 and 9 of the '062 patent are not obvious. The Limited defendants do not cite a reference that discloses orange oil as a cleaning component in a composition that cleans human skin. Nor do they identify timely activation, suggestion, or teaching to combine those references; hindsight is improper. The Board's 1996 record is addressed in D.I. 300. The Limited defendants' motion for summary judgment under Section 103 should be denied.

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Dated: July 21, 2006

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EXHIBIT 1

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ATTORNEY DOCKET NO.



FIRST HAMED INVENTOR

UNITED STA._8 DEPARTMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, O.C. 20231

07/413,395 09/27/89 GRIEENSPAN	
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	EXAMINER
TIMOTHY J. MARTIN	
44 UNION BLVD., STE. 620	SPEAR, J
LAKEWOOD, CO \$0228	ART UNAT PAPER NUMBER
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	DATE MAILED:
This is a covertunication from the examinal in charge of your application.	06/18/90
COLMISSIONER OF PATENTS AND TRADELIANS	33, 23, 75
This application has been exemined	This action is made final.
A shortened statutory period for response to this action is set to expire	days from the date of this letter,
Part 1 THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:	
LEGIT THE CALCULATE ALL AND MENTAL (2) NEE LAND OF 1988 WORNE.	
	re Patent Drawing, PTO-948,
	of Informal Patent Application, Form PTO-152
S. Information on How to Effect Drawing Changes, PTO-1474. 6.	
Part E SUMMARY OF ACTION	
1. 🖂 Claims - 8	
1 1 1 2 2	are pending in the application.
Of the above, claims	are withdrawn from consideration.
2. Cialms	have been canceled.
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4. L. Clains	are allowed.
4. 🛭 Claims 1-15	are rejected.
5. Cleins	are objected to.
6. Cialmsare	
7. This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are	
	acceptable for examination purposes.
8. Formal drawings are required in response to this Office action.	
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Serial No. 413,395

Art Unit 152

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This action is in response to the election with traverse of claims 1-15 submitted May 17, 1990 by Timothy J. Martin. The applicants arguments have bear considered but they are not deemed to be persuasive.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim I is rejected under 35 U.S.C. 103 as being unpatentable over Coleman, The Citrus Industry Pub:, November 1975.

Coleman shows a lotion hand cleaner comprising approximately 57% d-limonene, moisturizer (lanolin) and emulsifying agents (Arlacel and Tween). Although distilled citrus oil (94% d-limonene) is used it would be obvious to use orange oil, if it were not the source in this case. Page 24-25.

Claim 2 is rejected under 35 U.S.C. 103 as being

Serial No. 413,395

Art Unit 152

-3-

unpatentable over Coleman as applied to claim 1 above, and further in view of Dellutri US 4,620,937.

Dellutri shows a skin cleaner comprising d-limonene and further comprising aloe vera. To use aloe vera in the Coleman invention would be obvious since both inventors teach hand cleaners of similar compositions containing moisturizers. Col. 1, lines 60-65. Col. 3, lines 23-28.

Claims 3-7; 9-15 are rejected under 35 U.S.C. 103
as being unpatentable over Coleman and Dellutri as
applied to claim 2 above, and further in view of Juliano
et al US 4,014,995.

Juliano for claim 3 shows compositions for use on the skin containing oat flour. Juliano further shows oat flour as an emulsifier. Col. 1, lines 34-40. Col. 3, lines 16-25. To use the oat flour in the invention described above would be obvious in as much as the use of emulsifiers is a well recognized art. Nothing unobvious is seen by using oatmeal in claim 4, since oatmeal by definition is ground oats of a larger particle size than flour.

For claim 5 both Dellutri and Juliano teach compositions having a ph of 5.5. Juliano col. 2, lines 3-13, col. 3, lines 5-15. Dellutti col. 3, lines 52-59.

Serial No. 413,395

Art Unit 152

For claims 6-7 Juliano teaches the inclusion of substances to maintain a specific ph. Nothing un-obvious is seen in applicant' use of a ph range of 4.5-6, since the prior art shows the importance of ph balanced preparations for on the skinuse.

Claim 8 is rejected under 35 U.S.C. 103 as being unpatentable over Coleman, Dellutri, Juliano as applied to claims 1-7 above, and further in view of Jones US 4,5 33,487.

Jones shows the preparation of d-limonene containing buffers. The preparation is rendered harmless to the skin primarily due to the presence of the buffersSumCol. 3, lines 43-50. To use the buffered stable d-limonene preparations of Jones in the above mentioned inventions would be obvious in view of the prior art teachings. Note Dellutri's use of stabilized d-limonené. Col. 2, lines 19-23.

For claims 9-11 see Coleman, Dellutril and Juliano as applied to claim 3 above.

For claim 12 see Juliano as applied to claim 4 above.

For claims 13-15 see Coleman and Dellutri as applied to claim 2. Glycerin, aloe vera, jojoba oil and safflower oil are considered equivalents. Nothing un-obvious is seen in applicants use of mixtures.

Serial No. 413,395 Art Unit 152

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The motivation to produce cleaning compositions for use on the skin arises from the teachings of Coleman, Dellutri, Juliano and Jones who suggest the desirability to prepare cleaners comprised of orange oil having enhanced cleaning properties. The formulations are non-toxic, stable and non irritating to the skin. Claims 145 are rejected.

The Group and/or Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 150, Art Unit 152.

Any inquiry concerning this communication should be directed to James M. Spear at telephone number 703-557-6525.

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Spear:pla

(703) 557-6525

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Paper Number 5

Page 20 of 50

EXHIBIT 2

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GROUP 150
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Extent Application for reenspan and Low Al No.: 07/413,395 September 27, 1989

Filed: For: CLEANING COMPOSITIONS WITH ORANGE OIL

Date: September 18, 1990 Group: Art Unit 152 Examiner: J. Spear Action: AMENDMENT

The Commissioner of Patents and Trademark Office Washington, DC 20231

Sir:

In response to the Office Action of 18 June 1990, please reconsider the claims of this application in view of the following remarks:

REMARKS

These remarks are in response to the Office Action of 18 June 1990 in the above referenced patent application. In that application, Claims 1-18 were pending. However, Claims 16-18 were deemed withdrawn from consideration despite Applicants' traverse of the election.

Of the remaining claims, Claim 1 was rejected over Coleman, The Citrus Industry Publication, November 1975 under 35 U.S.C. Section 103. Claim 2 was rejected over Coleman in further view of U.S. Patent No. 4,620,937 to Dellutri under 35 U.S.C. Section 103. Claims 3-7 and 9-15 were rejected over Coleman and Dellutri in further view of U.S. 4,014,995 to Juliano. Claim 8 was rejected over the Coleman reference in view of Dellutri and Juliano and in further view of U.S. Patent No. 4,553,487 to Jones.

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At the outset, Applicants note with appreciation the thoroughness of the Examiner's comments in applying the cited references against the claims. However, Applicants have not amended their claims since they believe that the references teach away . from the present invention, as currently claimed, so that all of the claims in this application are allowable over these references. Applicants' position is supported by two arguments.

First, as the Examiner has noted, none of the cited references disclose the use of orange oil as a primary constituent. Rather, each of the references rely on the cleaning properties of d-limonene as the primary cleaning constituent. The Examiner then concludes that it would be obvious to substitute crange oil for the d-limonene since the d-limonene is distilled from a citrus oil.

Simply put, these references do not suggest the use of orange oil alone, but rather teach away from the use of orange oil since they rely on the distillate d-limonene. have found that undistilled orange oil has higher cleaning properties when used in a composition than distilled d-limonene. Applicants have tested the compositions produced according to the ranges of the present application wherein an equal weight percent of d-limonene was substituted for the orange oil. In each case, the orange oil based composition had superior cleaning properties than the identical composition with an equivalent amount of dlimonene substituted for the orange oil. While Applicants believe that other esters and volatiles in the orange oil may contribute to the enhanced cleaning properties, although the

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exact reason for the enhanced cleaning properties has not yet been determined. Nonetheless, Applicants have learned of a surprising result from the raw orange oil in these enhanced cleaning properties. This distinction over the use of d-limonene in the prior art is significant and not at all obvious. Indeed, Applicants have found that their composition is effective on substances such as urethane caulking, paint and tar that resist d-limonene cleaning compositions.

The enhanced cleaning property of orange oil contributes to the second distinction between the compositions recited in this application and the prior art. A review of the prior art shows that d-limonene is used in weight percentage ratios that are above the lower ratios claimed in the present application. These ratios run from a low of 51% d-limonene (Coleman) to a high of approximately 70% d-limonene (Coleman). Dellutri uses approximately 58%-60% d-limonene. As noted in the Coleman reference, citrus oil contains approximately 94% d-limonene so that the equivalent amount of citrus oil necessary to provide the amount of d-limonene in the prior art compositions run from approximately 55%-75%.

Claim 1 of the present application claims a range of 5% to 60% orange oil which, as noted above, allows for greater cleaning ability for lesser of the included cleaning agent (orange oil): Since the expense of orange oil is fairly substantial, this surprising result allows a reduction in the proportion of orange oil as opposed to d-limonene, and this leads to substantial economies.

A derivative benefit is seen where the quantity of orange oil, (and thus the amount of d-limonene) since studies have indicated that d-limonene may have carcinogenic effects. example, the attached study taken from the National Toxicology Study Program (January 1990) indicates a possible adverse effect from excess d-limonene. Where a cleaning composition is intended as one suitable for hand cleaning, as is the present invention. the benefits from reducing the quantity of d-limonene while maintaining the cleaning ability may be appreciated without further explanation.

Accordingly, all of the claims in this application are believed allowable for the inclusion of orange oil. several points directed to the dependent claims are in order since it is believed that the dependent claims contain allowable subject matter in their own right. In particular, those claims including the use of oat-grain derivatives and catmeal. Here, it has been found that the oatmeal may lend cleaning properties in that oatmeal acts as a drawing agent to help remove certain oils or other materials from the surface to be cleaned. It also adds abrasive quality to the cleaning compound to enhance the scrubbing ability.

Based on the foregoing, it is believed that this application conditioned for allowance and action to that end courteously solicited. Should the Examiner request any further information, in the form of affidavits or otherwise, regarding the matters addressed in this Amendment, the Examiner is invited to contact attorney for the Applicants at the telephone number

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listed below. Applicants would specifically request opportunity to submit such affidavits in the event that Examiner maintains the rejection of the present application.

Respectfully submitted,

TIMOTHY J. MARTIN, P.C.

Timothy J. Markh, #28.6 Dana Rewoldt, #P-33,762

44 Union Blvd., Suite 620 Lakewood, Colorado 80228

(303) 988-0800

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8

I hereby certify that the foregoing AMENDMENT is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to The Commissioner of Patents and Trademarks, Washington, DC 20231, on this day of September, 1990.

NTP TECHNICAL REPORT

ON THE

TOXICOLOGY AND CARCINOGENESIS STUDIES OF d-LIMONENE

(CAS NO. 5989-27-5)

IN F344/N RATS AND B6C3F1 MICE

(GAVAGE STUDIES)

C.W. Jameson, Ph.D., Study Scientist

NATIONAL TOXICOLOGY PROGRAM P.O. Box 12233 Research Triangle Park, NC 27709

January 1990

NTP TR 347

NIH Publication No. 80-2802

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service National Institutes of Health

Conclusions: Under the conditions of these 2-year gavage studies, there was clear evidence of carcino-genic activity* of d-limonene for male F344/N rate, as shown by increased incidences of tubular cell hyperplasis, adenomas, and adenocarcinomas of the kidney. There was no evidence of carcinogenic activity of d-limonene for female F344/N rate that received 300 or 600 mg/kg. There was no evidence of carcinogenic activity of d-limonene for male B6C3F₁ mice that received 250 or 500 mg/kg. There was no evidence of carcinogenic activity of d-limonene for female B6C3F₁ mice that received 500 or 1 non-matha. 1,000 mg/kg.

An increased severity of spontaneous nephropathy, increased incidences of linear mineralization of the renal modulia and papilla, and hyperplasia of the transitional epithelium of the cenal papilla were present in dosed male rate.

Bummary of the two-year gavage and denetic toxicology studies of alimonene

Male F346/N Rate	Female FMUN Rate	Maie B4C3F ₄ Mice	Female B6C3F ₁ Mice
Doors 6,76, or 180 mg/kg			
d-limocene in corn oil by gavage, 5 d/wk	0, 300, or 600 mg/kg & limotone in corn oil by gravege, & d/wk	6, 260, or 600 mg/kg d-limenses in corn eti by gavege, 6 d/wk	0,500, or 1,000 mg/kg d-listocene in corn ell by gevage, 5 d/ek
Body weights in the 2-year :	atude		
Approximately 6% reduction in high door group	Approximately 6% reduction in high does group	No effect.	10% reduction in high de- group by end of study
Burvivel rates in the 2-year 19/50; 33/60; 40/60	study 42/50; 40/50; 26/50	33/50; 24/50; 29/50	63/80; 64/60; 43/60
Nonneoptastic effects		•	••
Mineralisation (7/50; 43/50; (8/50) and epithelial hyper-	None	None .	None
pleaie (0/50; 25/50; 41/50) of the receil pepille; receil ubular cell hyperplacia 0/50; 4/50; 7/50)			
Yeophatie effects			
lonel tubular cell adeno- nas (0/50; 4/50; 8/50) and idenocarrinomas (0/50; 4/50; 1/50)	None	Kone	Hone
evel of evidence of carcino lear evidence		•	
MEL SAIDEROS	No avidence	No evidence	Ne evidence
ieselic texicology assays 5. typhinurium	Mouse LSi78Y/TK**	CHO Cella	To trie-
(Free metalion) Negative with and without 80	(Mi-resistance) Negative with and without 59	Negative with and without 50	Aberration Negative with and without 80

^{*}Explanation of Levels of Evidence of Carcinogenic Activity is on page 6. A summary of the Peer Review comments and the public discussion on this Technical Report appears on pages 9-10.

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Paper Number 6

EXHIBIT 3



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: Box ISSUE FEE COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

TIMOTHY J. MARTIN 44 UNION BLVD., STE. 620 LAKEWOOD, CO 80228

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

SERIES CONESERIAL NO.	FILEKSDATE	TOTAL CLARGE	EXA!	MINER AND GROUP	AT UNI	UATE MAR
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THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

- 1. Review the SMALL ENTITY Status shown above.
 - If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
 - A. If the Status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the Status is the same, pay the FEE DUE shown above.
- If the SMALL ENTITY is shown as NO:
- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.
- It. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE, Even if the ISSUE FEE has already been paid by a charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.
- III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Patents Issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees.

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Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

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TIMOTHY J. MARTIN 44 UNION BLVD., STE. 620 LAKEWOOD, CO 80228

EXAMINER SPEAR, J ART UNIT PAPER NUMBER DATE MALED:

04/18//91

NOTICE OF ALLOWABILITY

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PART L
1. A This communication is responsive to AMENAMENT FILED MAYCH 19, 1991
2. C) As the claims being stowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included harwith (or previously malled), a Notice Of Allowance and lesue Fee Due or other appropriate communication will be sent in the course.
1. 1/4. The allowed claims are 1-2, 4-9, 11 9 Nd 13-15
4. D The drawings filed onare scooplable.
5. [] Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [_] treen received. [_] not been received. [_] been filed in parent application Sariel No
6. S. Note the atlached Exeminer's Amendment.
7. Aloie the attached Examiner interview Summary Record, PTOL-413,
8. [] Note the attached Examiner's Statement of Reasons for Allowance.
9. O Note the attached NOTICE OF REFERENCES CITED, PTO-882.
6. El note the attached information disclosure citation, PTO-1448.
ARTIL
SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS ROM THE "DATE MAILED" indicated on this form, Fetture to timely comply will result in the ABANDONMENT of this application, xtensions of time may be obtained under the provisions of 37 CFR 1, 136(a).
"U note the strached EXAMINER'S AMENOMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the outhor dedication is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
APPLICANT MUST-MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
a. [] Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No.

Any response to this tetter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

c. CI Approved drawing corrections are described by the examiner in the sitsched EXAMINER'S AMENDMENT. CORRECTION IS

- Attachmenter
 L'Examiner's Amendment
- ... Examiner Interview Summery Record, PTOL 413

ts. \square The proposed drawing correction filed on

d.

Formal drawings are now REQUIRED.

- Reasons for Allowance
- ... Notice of References Clied, PTO-892 - Information Disclosure Citation, PTO-1449

REQUIRED.

REQUIRED,

- ... Notice of Informal Application, PTO-152
- ... Notice re Patent Drawings, PTO-948
- _ Listing of Bonded Draftsman

_ Other

____ ties been approved by the examiner. CORRECTION IS

Serial No. 413395

Art Unit 152

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with . Timothy J. Martin on April 5, 1991.

Non elected claims 16-18 have been cancelled by applicant. Applicant's amendment filed Harch 19,1991, now places application in condition for allowance.

Claims 1-2, 4-9, 11 and 13-15 are allowable over the prior art of record.

Any inquiry concerning this communication should be directed to James H. Spear at telephone number 703 308-2351.

J. H. Spear

04/5/91

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	UE FEE TRANS	1	15-2 5-50	~ ·
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Further correspondence to be mailed to the following:		ing on the patent front e names of not more than	1 Timoth	y J. Martin
Timothy J. Martin	3 registered	palent attorneys or		
44 Union Blvd., Suita 620 Lakewood, Colorado 80228		alternatively, the name of a as a member a registered	. s	
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(3) STATE OF INCORPORATION, IF ASSIGNEE IS A CORPORATION		Issue Fee Adv	anced Order - #	of Copies
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PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will app		in other fla	Mu)	Nuly 10, 1991
on the patent. Inclusion of assignee data is only appropriate whon an assignment has previously submitted to the PTO or is being submisted under separate cover. Complete	ion of lappi	E: fine issue fee wilfnot be a leane a registered attempy or	aneric or the assig	Née or other pains
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RE: Patent Application for Douglas H. Greenspan Serial No.: 07/413,395 Filed: September 27, 1989 For: CLEANING COMPOSITIONS

WITH ORANGE OIL

Dated: July 10, 1991 Group: Art Unit 152 Examiner: J. Spear Action: TRANSMITTAL OF BASE

ISSUE FEE

TO: Box Issue Fees The Commissioner of Patents and Trademarks Washington, DC 20231

Sir:

Enclosed is our check no. 1069 in the amount of \$540.00 (\$525.00 for Base Issue Fee plus \$15.00 for advance order of patent copies) along with the Base Issue Fee transmittal form PTOL-85b (Rev. 12-88). Formal drawings were previously submitted on 10 April 1991.

Respectfully submitted,

TIMOTHY J. MARTIN, P.C.

Zimothy J. Martin #21 Dana Rewoldt, #53,762 #28,640

44 Union Blvd., Suite 620 Lakewood, Colorado 80228

(303) 988-0800

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8

I hereby certify that the attached TRANSMITTAL OF BASE ISSUE FEE and check no. 1069 in the amount of \$540.00 is being deposited with the United States Postal Service as first-class mail in an envelope addressed to The Commissioner of Patents and Trademarks, Washington, DC 20231, on this 10 day of July, 1991.

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Product Data Sheet Material Safety Data Sheet

ORIDA CHEMICAL CO., INC.

351 Winter Haven Blvd. NE Winter Haven, FL 33881-9432

> Phone; (863) 294-8483 Fax: (863) 294-7783

Web Site: www.florjdachemical.com E-Mail: info@flocidachemical.com

PRODUCT DATA SHEET

Preparation Date: April 2005

DESCRIPTION

Cold Pressed Orange Oil is the essential oil obtained from the expression of ripe orange fruit peel. Early/Midseason Cold Pressed Orange Oil comes from common orange varieties including Hamlin and Pineapple oranges. Valencin Cold Pressed Orange Oil is restricted to the late season Valencia fruit.

APPEARANCE & ODOR

Bright and clear yellow to orange liquid. Early/Midseason tends to have slightly darker color. Characteristic odor of the fresh, sweet

USES & APPLICATIONS

Current d-Limonene formulators will find that Cold Pressed Orange Oil is an effective and economic way to add color and extra citrus aroms to their product. Cold Pressed Orange Oil is a food product with a history of uses in the flavor and fragrance industry. Examples include use as an ingredient in fruit flavors and floral perfume compositions. Cold Pressed Orange Oil is a common additive to many products requiring citrus flavor because of the characteristic sweet & fresh citrus notes.

REGULATORY STATUS

d-Limonene (main component of Cold Pressed Orange Oil) has been designated as GRAS (Generally Recognized as Safe) by the Food and Drug Administration. The EPA has granted d-Limonene an exemption from the requirement of a tolerance when it is an inert ingredient used as a solvent or fragrance in pesticide formulations, d-Limonene is not considered a carcinogen, a developmental toxicant or mutagenic, d-Limonene is not listed on CA Proposition 65, Cold Pressed Orange Oil is an approved food ingredient listed in the FCC.

Cold Pressed Orange Oil is a naturally occuring VOC. Cold Pressed Orange Oil is reportable on average as 95% VOC (850 grams per litre, 6.8 lbs per gallon). Emulsions containing Cold Pressed Orange Oil can be exempt from VOC regulations. Contact state VOC or regulatory authorities for ruling.

<u>PACKAGING</u>

Cold Pressed Orange Oil is packaged in epoxy-lined comainers as follows:

1-Gallon Pui!

7 Pounds Net Weight

3.2 kg Net Weight

5-Gallon Pail 55-Gallon Dram

35 Pounds New Weight 390 Pounds Not Weight 16 kg Net Weight

177 kg Net Weight

Packaging continued next page

BBW 009097

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Drums are typically orange or black DOT approved steel drams coated with an epoxy-phenotic resin liner. All drams of our Cold Pressed Orange Oil are filled to a net weight of 390 lbs. Dimensions of 55-gallon drams are: length 23", width 23", and depth 35". Tank truck shipments average 6500 gallons (45,000 lbs). Overseas ISO tank shipments are either 20,000 liters (16,800 kg) or 24,000 liters (20,160 kg). Sample quantities are packaged in fluorinated plastic containers or glass (1 oz. samples).

STORAGE & HANDLING

Store in a warehouse with a fire prevention system. Avoid contact with incompatible chemicals listed in Section IV. Store in tightly scaled full containers in well-ventilated controlled warehouse conditions, Partially filled containers should be blankered with nitrogen, Antioxidants such as BHT are commonly used in addition to proper storage and handling procedures.

Improper storage and handling can lead to oxidation. Cold Pressed Ocange Oil is "winterized" when it is first produced by storing at freezing temperatures to remove the majority of natural waxes. Although this process is done as thoroughly as possible, trace announts of waxy solids may remain and settle out of the product when stored for an extended period of time, particularly in cold temperatures.

Cold Pressed Orange Oil samples and certificates of analysis are available upon request.

Caution: The user should conduct his/her own experiments and establish proper procedures and controls before attempting use on critical parts,

Cold Pressed Orange Oil

MATERIAL SAFETY DATA SHEET

Preparation Date: April 2005

Emergency Phone Numbers: Piorida Chemical: (863) 294-8483 CHEMTREC 24 Hour Number: (800) 424-9300 Outside U.S., call CHEMTREC collect

FLORIDA CHEMICAL

351 Winter Haven Blud, NE Winter Haven, FL 33881-9432 Phone: (863) 294-8483 Fax: (863) 294-7783 Neb Site: www.floridachen E-Mail: hifo@flaridochemical.com



Trade Name: Cold Pressed Orange Oil Early Midserson & Valencia Product Codes: 330000-Early/Midseason 331000-Valencia 329000-Orange Oil Blend CAS Number: 8028-48-6 EINECS Number: 232-433-8

Serion (SHAZARDO) (SCOVIZONENTS)

Volatile Ingredients: D-Limonene is the major component >90% of Early/Midseason and Valencia Orange Oil, Cold Pressed Orange Oil is a by-product of citrus, entirely of natural origin, and to the best of our knowledge and belief contains no artificial flavors, sulfiles, artifiles, or pesticide residue exceeding tolerances established by the FDA. Cold Pressed Orange Oil does NOT contain lead, cadmium, mercury, or hexavalent chromium or come in contact with these chemicals since it is a citrus-derived essential oil expressed from orange peels. Further, Cold Pressed Orange Oil is packaged in food grade contained with ment liners that do NOT contain lead, cadmium, measury, or bexavelent chromium. Cold Pressed Orange Oil does NOT contain and is NOT manufactured with any Class I or II ozone-depleting substances listed under the United States Clean Air Act of 1990.

Hazardous Materials Identification System - HMIS:

- Health Hazard Mild side irritent
 - Flammability Flashpoint above 100°F Reactivity Stable
- G
 - Protection Safety glasses & gloves recommended

This substance contains no materials subject to the reporting requirements of SARA TITLE III SECTION 313.

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 Appearance
 Light yellow-orange oil

 Odor
 Fresh orange aroun

 Specific Gravity (25°C)
 0.842 - 0.846

 Refractive Index (20°C)
 1.4720 - 1.4740

 Optical Rotation (25°C)
 +94° - +99°

 Aldehyde, % (as decyl)
 1.0 - 2.0

Flashpoint (CCCFP)

Boiling Point

Bvaporation Rate

Vapor Perssure (20°C)

Percent Votatile by Volume

>10°F ASTM D6450

349°F (176°C)

Bvapor After Co. (BuAc=1)

Insoluble

Over 1

Vapor Pressure (20°C)

Percent Votatile by Volume

98%

Section IV FERE AND EXELOSION PLAZARD DATAS TO SECTION FOR THE SECTION OF THE SEC

Plashpoint (CCCFP): >110°F ASTM D6450.

Flammable Limits: LEL = Not Available. UEL = Not Available. Extinguishing Meida: Carbon dioxide, foam or dry chemical.

Special Fire Fighting Procedures: SCBA recommended. Smother to exclude air. Do not use water. Handle as an oil fire.

Unusual Mre and Explosive Hazards: Combustible liquid. Keep away from heat, sparks, and open flame.

Incompatibility (Materials to avoid): Strong oxidizing agents.

Hazardous Decomposition Products: Not Available.

Hazardous Polymerization: Will not occur.

Conditions to Avoid for Polymerization: Not Available.

Stability Considerations: Stable.

Conditions to Avoid for Stability: Avoid temperatures over 118°F (48°C).

Second Have Management of the Control of the Contro

Health Hazards (Acute and Chronic): Product is a moderate irritant, moderate ingestion and slight inhalation hazerd under acute local application.

This Product Contains No Carcinogens (NTP, IARC or OSHA).

Signs and Symptoms of Exposure: Product may be initiating to the skin, eyes, nose and throat.

Medical Conditions Generally Aggravated by Exposure: Persons with allergies or pre-existing skin conditions should avoid contact with this product.

CONTRACTOR CONTRACTOR

Eye Coutact: Remove contact leases at once. Immediately flush eyes with large quantities of clean water for at least 15 minutes. Call a physician immediately.

Skiu Contact: Remove any contaminated clothing or shoes. Thoroughly wash affected area with soap. Flush with large quantities of clean water. If infundon develops or persists, call a physician.

Ingestion: DO NOT induce vomiting. Administer water and eait a physician or local Poison Control Center immediately. Inhalation: Remove to fresh air and cumuct a physician immediately.



Steps to be Taken if Material is Released or Spilled: Use protective gloves to avoid skin contact. Small spills can be wiped up. Large spills should be absorbed by dirt, sand or other suitable absorbents for disposal. Do not hose spills down drains, sewers or waterways. Cold Pressed Orange Oil may be toxic to aquatic organisms. Move leaking containers to well ventil and area. No smoking, Eliminate any source of leation. Minimize inhalation. Use NIOSH approved protection device. CAUTION: slippery on floor.

Waste Disposal Method: Incinerate or Dispose in Accordance with Local, State and Federal Regulations.

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Drams are typically mange or black DOT approved steel drams coated with an epoxy-phenolic resin liner. All drams of our Cold Pressod Orange Oil are filled to a net weight of 390 lbs. Dimensions of 55-gallon drums are: length 23", width 23", and depth 35". Tank truck shipments average 6500 gallons (45,000 lbs). Overseas ISO tank shipments are either 20,000 liters (16,800 kg) or 24,000 liters (20,160 kg). Sample quantities are packaged in fluorinates plastic containers or glass (1 oz. samples).

STORAGE & HANDLING

Store in a warehouse with a fire prevention system. Avoid contact with incompatible chemicals listed in Section IV. Store in tightly scaled full comminers in well-ventilated controlled warehouse conditions. Partially filled comminers should be blankered with nitrogen. Anticuidants such as BHT are commonly used in addition to proper surrage and handling procedures.

Improper storage and handling can lead to exidation. Cold Pressed Orange Oil is "winterized" when it is first produced by storing or freezing temperatures to remove the majority of manual waxes. Although this process is done as thoroughly as possible, trace amounts of waxy solids may remain and sende out of the product when stored for an extended period of time, particularly in cold temperatures.

Cold Pressed Orange Oil samples and certificates of analysis are available upon request.

Caution: The user should conduct his/her own experiments and establish proper procedures and controls before attempting use on critical parts.

Cold Pressed Orange Oil

MATERIAL SAFETY DATA SHEET

Preparation Date: April 2005

Emergency Phone Numbers: Floride Chemical: (863) 294-8483 CHEMTREC 24 Hour Number: (800) 424-9300 Outside U.S., call CHEMIREC collect

FLORIDA CHEMICAL CO.

351 Winter Haven Blvd. NE Winter Haven, FL 33881-9432 Phone: (863) 294-8483 Fax: (863) 294-2783 Web Site: www.floridache E-Mail: Info@floridacisemical com

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Trade Name: Cold Pressed Orange Oil -Enrly/Midsenson & Volencia

Product Codes: 330000-Early/Midscason 331000-Valencia 329000-Orange Oil Blend

CAS Number: 8028-48-6 EINECS Number: 232-433-8

SECONDECTAZARDOUS GOVEONES

Volatile Ingredients: D-Limonene is the major component >90% of Early/Midseason and Valencia Orange Oil. Cold Pressed Orange Oil is a by-product of citrus, entirely of natural origin, and to the best of our knowledge and belief contains no artificial flavors, sulfites, mirrites, or pesticide residue exceeding tolerances established by the FDA. Cold Pressed Orange Oil does NOT contain lead, cadmium, measury, or hexavalent chromium or come in contact with these chemicals since it is a citrus-derived essential oil expressed from orange pecis. Further, Cold Pressed Orange Oil is packaged in food grade containers with inen liners that do NOT contain lead, cadmium, mercury, or hexavatera chromium. Cold Pressed Ocange Oil does NOT commin and is NOT manufactured with any Class I or II ozone-depleting substances listed under the United States Clean Air Act of 1990.

Hazardous Materials Identification System - HMIS:

- Health Hazard Mild skin irritant

- Flanmability Flashpoint above 100°F Reactivity Stable Protection Safety glasses & gloves recommended

This substance contains no materials subject to the reporting requirements of SARA TITLE III SECTION 313.

CERTIFICATE OF SERVICE

I hereby certify that on the 27th day of July, 2006, the attached REDACTED PUBLIC VERSION OF LP MATTHEWS' OPPOSITION TO BATH & BODY WORKS, INC.'S AND LIMITED BRANDS, INC.'S MOTION FOR SUMMARY JUDGMENT OF INVALIDITY UNDER 35 U.S.C. § 103 was served upon the below-named counsel of record at

Richard L. Horwitz, Esquire Potter Anderson & Corroon, LLP Hercules Plaza, 6th Floor 1313 North Market Street Wilmington, DE 19801

the address and in the manner indicated:

HAND DELIVERY

Arthur I. Neustadt, Esquire Oblon, Spivak, McClelland, Maier & Neustadt, P.C. 1940 Duke Street Alexandria, VA 22314 VIA FEDERAL EXPRESS

Francis G.X. Pileggi, Esquire Fox Rothschild LLP Suite 1300 919 North Market Street Wilmington, DE 19801 HAND DELIVERY

John Ward, Esquire Ward & Olivo 708 Third Avenue New York, NY 10017

VIA FEDERAL EXPRESS

/s/ John G. Day

John G. Day